

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Edward N. Barthell	Art Unit:	3686
Serial No.:	10/649,127	Examiner:	Sheetal Rangrej
Filing Date:	August 27, 2003	Conf. No.:	4764
Title:	<i>Bio-Surveillance System and Method</i>		

SUPPLEMENTAL DECLARATION UNDER 37 C.F.R. § 1.131

Commissioner For Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

I, Edward N. Barthell, MD, declare:

1. I am the inventor of the subject matter of the above-identified U.S. Patent Application ("the invention").
2. I have reviewed the claims of this Application.
3. I conceived the invention in the United States during the fall of 2001 and, in any event, prior to March 26, 2002, the filing date of U.S. Published Patent Application No. 2003/0187615 entitled *Methods and Apparatus for Early Detection of Health-Related Events in a Population*, the invention as set forth in the aforementioned claims.
4. The following facts and evidence are submitted in support of this declaration in addition to the facts and evidence previously provided in the Declaration filed March 17, 2007 and in the Supplemental Declaration filed February 12, 2008 in the above-captioned matter with the United States Patent and Trademark Office.
5. I discussed the invention with a number of leaders of the American College of Emergency Physicians (ACEP) at their annual scientific assembly held in

Chicago from October 15-18, 2001. Specifically, I discussed the invention at the EM Informatics section meeting, minutes of which are believed to be recorded in the files of ACEP.

6. Two of the named inventors of the 2003/0187615 patent application, Mark Crockett and John Epler, worked for ibex Healthdata Systems, Inc. at the time of the ACEP meeting.

7. Ibex Healthdata Systems, Inc. also exhibited at the meeting and it is very likely that at least one of the two inventors named in the '615 application attended my presentation. Enclosed as Appendix A is an archived press release which identifies the named inventors as employees of ibex Healthdata Systems, Inc. and reports that ibex Healthdata Systems, Inc. exhibited at the conference. I strongly suspect that the '615 application is based at least in part on information obtained from me at the meeting.

8. In 2002, the assignee, Infinity Healthcare, was a very small company having no full time employees. The "Frontlines of Medicine" or simply "Frontlines" project serving as the basis of the invention was manned solely by myself and a few other physicians working on a volunteer basis. We were full time emergency care clinicians and had only limited time to devote to the Frontlines project. I estimate that the demands of my professional related activities left me with, on average, no more than 4-6 hours a week to devote to the Frontlines project, and that time was unevenly distributed during the period in question due to my work schedule. Some days the demands of my primary position as an emergency care physician left me little or no time at all to devote to the Frontlines project.

9. Nevertheless, prior to April 19, 2002, I diligently collaborated in planning, organizing and managing a conference to develop a consensus for standardized tools and procedures for reducing to practice the Frontlines concept that I had previously conceived. Details of this work are included in my prior declaration submitted February 12, 2008.

10. In preparation for the aforementioned conference, eight other emergency care physicians and I each solicited feedback from 3-5 other individuals believed to have experience in fields relating to the Frontlines project. We set a deadline of April 15, 2002 for the delivery of that feedback.

11. Between April 19, 2002 and July 30, 2002, I worked diligently to refine the invention to the point that I felt it was ready for patenting. A significant portion of the work during this period included following up with and evaluating the feedback received from the individuals mentioned in paragraph 10 as well as feedback from participants in the conference. Evidence of this work is supported, at least in part, by email messages sent to and from individuals participating in the survey. Details from a selection of emails during this time period, as outlined below, demonstrate my diligence in reducing the invention to practice.

- A. April 19, 2002: I received feedback regarding the Health Insurance Portability and Accountability Act (HIPAA) privacy and security requirements.
- B. April 24, 2002: I forwarded the most recent list of categories for triage data for each patient to a colleague for review. I received feedback from this colleague regarding the categories for triage data as well.
- C. April 28, 2002: A Frontlines project meeting was held in Washington D.C. at which about 65 people attended (see also May 15, 2009).
- D. April 29, 2002: I requested that each of the presenters from the Washington D.C. meeting forward their slide presentations to be compiled as a reference resource for other collaborators.
- E. May 2, 2002: I received a reply to an email proposing pilot projects for the Frontlines project. The original email indicates that the plans will be developed over the coming weeks and the reply email provides suggestions for funding sources.
- F. May 3, 2002: I inquired about the possibility to incorporate the Frontlines project into a web-based tracking system at Northwestern University.
- G. May 4, 2002: I received a reply indicating interest in incorporating the Frontlines project with Northwestern University's tracking system.

- H. May 13, 2002: A proposed agenda for a conference call identifies ongoing work in developing the list of complaint codes for triage information.
- I. May 15, 2002: I referenced the April 28th Frontlines project meeting and acknowledge ongoing feedback from participants at the meeting. I also identify a "to-do" list for ongoing development of the Frontlines project, including identifying triage data elements.
- J. May 30, 2002: I received an email expressing interest to further develop the Frontlines project and the list of triage data.
- K. June 4, 2002: I drafted an email identifying that an initial list of complaints for the Frontlines project has been compiled and that the next stages of development include producing a web service, or network, to facilitate data collection.
- L. June 7, 2002: I received feedback regarding triage data elements and establishing pilot program for data collection.
- M. June 16, 2002: I received additional feedback regarding triage data elements.
- N. June 18, 2002: I received still additional feedback regarding triage data elements.
- O. June 22-24, 2002: I was arranging to discuss the bioterrorism bill with a doctor at the Center for Disease Control (CDC).
- P. July 07, 2002: I received additional feedback regarding triage data elements.
- Q. July 11, 2002: I received still additional feedback regarding triage data elements.
- R. July 12, 2002: I sent an email to select Frontlines project survey participants indicating the first round of survey results had been compiled and forwarded the results for additional comment.
- S. July 15, 2002: I received feedback regarding triage data elements from one of the select participants emailed on July 12, 2002.

T. July 17, 2002: I sent an email to all Frontlines project survey participants with the first-round survey results, seeking additional feedback to be submitted by August 7, 2002.

12. The above-referenced emails demonstrate a continuous and ongoing effort to solicit, receive, and evaluate feedback regarding the Frontlines project in order to reduce the concept to practice. For example, a significant amount of work was directed to refining and developing the triage data elements to be utilized in the Frontlines project.

13. Upon completion of the first-round survey analysis and results on or about July 16, 2002, I decided that the invention was sufficiently refined to proceed with the preparation of a United States patent application.

14. From on or about July 16, 2002 to October 11, 2002, I diligently worked with my attorneys to evaluate the potential patentability of my invention to prepare and file a patent application. Details of this work are included in my prior declaration along with a declaration from my patent attorney, Timothy Newholm, both declarations submitted on February 12, 2008.

15. During the entire period referenced above, I remained employed as a full-time emergency medical clinician. While my other obligations prevented me from working on the Frontlines project continuously during that period, I believe that no more than a few days at any given time went by without me making some efforts to refine the invention to the point I felt that it was ready for patenting.

16. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,



Edward N. Barthell, MD